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VI. 510(k) SUMMARY FOR THE BARD® TAPERSEAL® IAB CATHETERS

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter Information

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B. Device Name

Trade Name: Bard® TaperSeal® IAB Catheters
Common/Usual Name: Intra-Aortic Balloon Catheter
Classification Name: Intra-Aortic System, Balloon, Intra-Aortic and Control

C. Predicate Device

Trade Name: Sheathless 40cc Pre-Wrapped Double-Lumen 9.0 F. Intra-Aortic Balloon Catheter. (Model IAB-04240S)

D. Device Description

Each double lumen percutaneous TaperSeal® IAB catheter is pre-furled and has a hemostasis device attached to the catheter which may be slid down the catheter and into the insertion site as necessary in the event of excessive bleeding from the puncture site. Each TaperSeal® IAB catheter is packaged into a balloon kit that contains airway tubing, a syringe, syringe adaptor, Kontron and/or Datascope adaptor, and pressure tubing with a stopcock. The TaperSeal® IAB catheters also come packaged with an insertion kit which contains a percutaneous tear away introducer, two guidewire, an angiography needle, and a vessel dilator.

E. Intended Use

- Refractory left ventricular failure,
- Cardiogenic or septic shock,
- Unstable refractory angina,
- Impending infarction,

- Ischemia related ventricular arrhythmias,
- Weaning from cardiopulmonary bypass,
- Support and stabilization during coronary angioplasty,
- Intraoperative pulsatile flow generation,
- Associated mechanical complications of acute myocardial infarction,
- Support and stabilization of high-risk patients undergoing general surgical procedures.

F. Technological Characteristics Summary

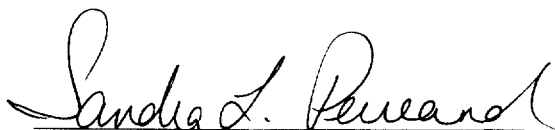
Both the TaperSeal and Arrow IAB catheters are very similar, with only a few minor differences with respect to design and materials.

Table VI-1 Comparison of General Characteristics

Characteristic	Bard® TaperSeal® 30cc & 40cc IAB Catheters	Arrow Sheathless 40cc Pre-Wrapped Double-Lumen 9.0 F. IAB Catheter
Balloon Membrane	Polyurethane/Silicone	Polyurethane/Silicone (Cardiothane™)
Outer Lumen	Polyurethane	Polyurethane
Inner Lumen	Stainless Steel coiled around a Polyurethane tube	Stainless Steel Tube
Catheter Tip	Polyurethane	Stainless Steel
Bifurcation	Polycarbonate	Polyolefin
Tracer Ring	Stainless Steel	None
Tie down	Thermo Plastic Elastomer	Thermo Plastic Elastomer
Hemostasis Device	Polyolefin	Polyolefin
Hemostasis seal	Silicone	None
Hemostasis Cap	Nylon	None

G. Performance Data

Bench testing was performed to verify that the TaperSeal Catheter can withstand insertion forces associated with sheathless insertion. All testing was completed successfully.



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Regulatory Affairs Program Manager

9/3/96

Date